Mercy Investment Program

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January 24, 2005

Docket ID 2004D-0369

Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by Bioengineered Plants Intended for Food Use.

FDA Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane , Room 1061
Rockville , MD 20852

To Whom It May Concern:

I am writing on behalf of the Dominican Sisters of Hope, Mercy Investment Program, the Sisters of Mercy-Regional Community of Detroit and the Ursuline Sisters of Tildonk-U.S. Province, all of which are shareholders in corporations, which are part of our food system from seed to final product.

We, as shareholders, are taking the opportunity to comment on the Draft Guidance: Recommendations for Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by Bioengineered Plants Intended for Food Use.

For the past five years, faith-based investors have been raising questions and filing shareholder resolutions about the safety of genetically engineered foods. We have urged disclosure of gmo ingredients and food products. We've questioned the lack of long-term testing of the impact of gmo foods on children and adults. With respect to gmo seeds, we've suggested there are problems with containment, impact on seed variety and organic planting as well as use of pesticides.

We believe the FDA should not continue with a voluntary process. Safety evaluation of foods from bioengineered plants should be mandatory. Consumer and other groups, in addition to shareholders, have consistently urged a mandatory process. Nothing in this voluntary process, or this draft guidance, protects the public. With no legal enforceability

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and no requirements, there is no effective oversight or effective evaluation

The draft guidance indicates that if a "protein has been evaluated in an early food safety evaluation and no safety concerns are identified, ...[FDA] would not expect additional food safety evaluation to be submitted if the same protein is introduced into another plant species." This statement ignores the fact that proteins can act differently in different species and organisms and would, in effect, allow all novel genes in bioengineered non-pesticidal plants in field tests to be considered safe in foods. We believe this guidance weakens the FDA system for bioengineered foods.

Again, the FDA's consultation process for bioengineered foods must be mandatory, not voluntary.

We complement the FDA for its decision to make submissions of early food safety evaluations for new proteins, and FDA's responses, easily accessible to the public via the internet.

Thank you for your attention.

Yours truly,

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